

武 汉 远 大 弘 元 股 份 有 限 公 司

W U H A N G R A N D H O Y O C O . , L T D .

WUHAN GRAND HOYO CO., LTD. QUALITY CONTROL

武汉远大弘元股份有限公司

检验专用章(3)

C 仅供检验使用, 其他无效

Industrial Park, Gedian Economy Development Zone, Hubei

Tel.: +86-27-87455429

METAPHARMACEUTICAL

N DE LOTE:

0190925

10/09/2025

产品名称: N-乙酰-L-半胱氨酸(非动物源/素食)

Product: N-Acetyl-L-Cysteine(NON-ANIMAL SOURCE/VEGAN) 批 号 Lot No: C103-202505808F

批 量 Quantity:1000kg

报告日期 Report Date: MAY 08,2025

Item 项目		Specification 标准	Result 检测结果	
性状 Characters		白色或类白色，结晶性粉末或无色结晶，易溶于水和 96%乙醇，几乎不溶于二氯甲烷。White or almost white, crystalline powder or colourless crystals, freely soluble in water and in ethanol (96 percent), practically insoluble in methylene chloride.	符合 Conforms	
鉴别 Identification	Test A (Specific Optical rotation)	应符合比旋度标准要求。It complies with the test for specific optical rotation.	符合 Conforms	
	Test C (IR)	本品的红外光谱图谱应与乙酰半胱氨酸标准品红外图谱一致。It complies with the spectrum obtained with acetylcysteine CRS.	一致 Identical	
溶液外观 Appearance of solution		澄清无色 Clear and colourless	澄清无色 Clear and colourless	
比旋度[α] _D ²⁰ Specific optical rotation [α] _D ²⁰		+21.0° to +27.0°	+23.6°	
相关物质 Related substances		杂质 B ImpurityB L-半胱氨酸 L-Cysteine ≤0.2%	<0.05%	
		杂质 C ImpurityC N,N-Diacetyl-L-Cystine ≤0.3%	<0.05%	
		杂质 D ImpurityD N,S-Diacetyl-L-Cysteine ≤0.15%	<0.05%	
		其他杂质 Unspecified impurities	杂质 A ImpurityA L-胱氨酸 L-Cystine ≤0.10%	<0.05%
			其他未知杂质 Any other impurity ≤0.10%	<0.05%
		总杂质 Total ≤0.5%	0.08%	
干燥失重 Loss on Drying		≤0.5%	0.1%	
炽灼残渣 Sulfated ash		≤0.2%	0.08%	
含 量 Assay		98.5 to 101.0 % （dried substance）	99.8%	
重 金 属 Heavy metals(Pb)		≤10ppm	<10ppm	
锌 Zinc		≤5ppm	<5ppm	
pH		2.0 to 2.8	2.3	
铅 Lead		≤ 2ppm	<2ppm	
镉 Cadmium		≤ 1ppm	<1ppm	
汞 Mercury(Hg)		≤ 0.1ppm	<0.1ppm	
砷 Arsenic(as As ₂ O ₃)		≤ 1ppm	<1ppm	
残留溶剂 Residual Solvents		meet the requirements	Conforms	
粒度 Particle Size		100% pass 20Mesh	Conforms	
Tapped Density		0.75-0.85g/ml	0.85g/ml	
Total Plate Count		< 1000cfu/g	Conforms	
Yeast & molds		< 100cfu/g	Conforms	
Salmonella		Negative/25g	Conforms	
E Coli		Negative/25g	Conforms	

Staphylococcus	Negative/25g	Conforms
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结论：本品按 EP11&USP39 标准检验，结果符合规定。Conclusion: Comply with the specification of EP11&USP39.

备注 Remarks: Vegan/Non Animal Source. For food use only, not for API grade.

STORAGE CONDITIONS: PRESERVE IN TIGHT CONTAINERS AT CONTROLLED ROOM TEMPERATURE

生产日期：2025 年 04 月 27 日

复验期：2028 年 04 月 26 日

Manu. Date: APR 27,2025

Retest Date: APR 26,2028

检验报告员 Inspector: 陈彩虹 复核人 Auditor: 赵敏 质检部负责人 Chief of QC: 张婷